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SYNTHES®

Revised 510(k) Summary

JUN 17 2009

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Contact: Sheri L. Musgnung
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940
FAX (610) 484-356-9682

Device Name: Synthes Angular Stable Locking System (ASLS)

Classification: Class II, §888.3020 – Intramedullary fixation rod

Predicate Device: Synthes 3.9 mm Ti Locking Bolts
Synthes 4.9 mm Ti Locking Bolts
Synthes 6.0 mm Locking Screws

Device Description: Synthes Angular Stable Locking System (ASLS) is designed as an alternative device for the interlocking of Synthes Cannulated Titanium Intramedullary Nails. The ASLS consists of a titanium screw with a 70:30 Poly (L/DL-Lactide) sleeve and is available in diameters ranging between 4.0 mm – 6.0 mm and overall lengths ranging between 23 mm – 125 mm.

Intended Use: The Synthes Angular Stable Locking System (ASLS), when used with Synthes Cannulated Titanium Intramedullary Nails, is intended to aid in the alignment and stabilization of tibial, humeral, femoral, and ankle fractures.

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Synthes (USA)
% Ms. Sheri L. Musgnung
Regulatory Affairs Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K090241
Trade/Device Name: Synthes Angular Stable Locking System (ASLS)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: June 10, 2009
Received: June 11, 2009

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler for

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SYNTHES®

Revised Indications for Use

510(k) Number (if known): K090241

Device Name: Synthes Angular Stable Locking System (ASLS)

Indications for Use:

The Synthes Angular Stable Locking System (ASLS), when used with Synthes Cannulated Titanium Intramedullary Nails, is intended to aid in the alignment and stabilization of tibial, humeral, femoral, and ankle fractures.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MAN

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090241